

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

This Document Relates to All Actions

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Oral Argument Requested

**TPP TRIAL DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF
MOTION TO EXCLUDE THE OPINIONS OF DR. RENA CONTI**

TABLE OF CONTENTS

	<u>Page</u>
PRELIMINARY STATEMENT	1
BACKGROUND	3
I. Dr. Conti's Worthlessness Assumption.....	4
II. Dr. Conti's Damages Calculations	5
A. The Class Calculations.....	5
B. The Named Plaintiff's Calculation	10
III. Dr. Conti's Point-of-Sale Method	11
ARGUMENT.....	13
I. DR. CONTI'S CLASS-WIDE CALCULATIONS DO NOT FIT THE FACTS OF THE UPCOMING CLASS TRIAL.....	13
II. DR. CONTI'S OPINION THAT THE VCDS WERE WORTHLESS IS UNRELIABLE.....	16
III. DR. CONTI'S DAMAGES CALCULATIONS ARE UNRELIABLE.....	21
A. Dr. Conti's Estimated Damages Are Wildly Overbroad Because She Did Not Consider Various Offsets Under Medicare Part D.	21
B. Dr. Conti's Reliance On IQVIA Data For Calculating Class- Wide Damages Is Unreliable.....	25
CONCLUSION	32

TABLE OF AUTHORITIES**Page(s)****CASES**

<i>In re Acetaminophen - ASD-ADHD Products Liability Litigation</i> , MDL No. 3043, 2023 U.S. Dist. LEXIS 224899, --- F. Supp. 3d ---- (S.D.N.Y. Dec. 18, 2023).....	13
<i>American Federation of State County & Municipal Employees, District Council 47 Health & Welfare Fund v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.</i> , 857 F. Supp. 2d 510 (E.D. Pa. 2012).....	17
<i>Amorgianos v. National Railroad Passenger Corp.</i> , 303 F.3d 256 (2d Cir. 2002).....	25
<i>Blue Cross Blue Shield Ass’n v. GlaxoSmithKline LLC</i> , No. 13-4663, 2019 WL 4751883 (E.D. Pa. Sept. 30, 2019).....	17, 18
<i>Center City Periodontists, P.C. v. Dentsply International, Inc.</i> , 321 F.R.D. 193 (E.D. Pa. 2017)	13, 14, 16
<i>Comcast Corp. v. Behrend</i> , 569 U.S. 27 (2013).....	14
<i>Duroskey v. United States</i> , No. 3:CV-07-1828, 2008 WL 5104850 (M.D. Pa. Dec. 1, 2008)	25
<i>Edison Wetlands Ass’n v. Akzo Nobel Chemicals, Inc.</i> , No. 08-419 (FSH), 2009 WL 5206280 (D.N.J. Dec. 22, 2009)	21
<i>Elcock v. Kmart Corp.</i> , 233 F.3d 734 (3d Cir. 2000).....	21
<i>General Electric Co. v. Joiner</i> , 522 U.S. 136 (1997).....	29

<i>Johnson Electric North America Inc. v. Mabuchi Motor America Corp.</i> , 103 F. Supp. 2d 268 (S.D.N.Y. 2000)	20
<i>Lippe v. Bairnco Corp.</i> , 99 F. App'x 274 (2d Cir. 2004)	28
<i>In re Niaspan Antitrust Litigation</i> , 67 F.4th 118 (3d Cir. 2023)	10
<i>In re Rezulin Products Liability Litigation</i> , 210 F.R.D. 61 (S.D.N.Y. 2002)	16, 17
<i>Oklahoma Land Holdings, LLC v. BMR II, LLC</i> , No. CIV-17-1036-D, 2020 WL 1236307 (W.D. Okla. Mar. 13, 2020)	26, 27
<i>Sardis v. Overhead Door Corp.</i> , 10 F.4th 268 (4th Cir. 2021)	18
<i>Second Amendment Arms v. City of Chicago</i> , No. 10-cv-4257, 2020 WL 1157347 (N.D. Ill. Mar. 10, 2020)	26
<i>Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP</i> , 20 F. Supp. 3d 305 (E.D.N.Y. 2014)	17
<i>Sines v. Darling Ingredients Inc.</i> , No. 19-19121, 2023 WL 3841741 (D.N.J. June 6, 2023)	27
<i>Soldo v. Sandoz Pharmaceuticals Corp.</i> , 244 F. Supp. 2d 434 (W.D. Pa. 2003)	25
<i>United States v. Zimmerman</i> , 277 F.3d 426 (3d Cir. 2002)	13
<i>In re Valsartan, Losartan, & Irbesartan Products Liability Litigation</i> , No. 19-2875 (RBK/SAK), 2023 WL 1818922 (D.N.J. Feb. 8, 2023)	2, 16, 17

<i>In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation</i> , 858 F.3d 787 (3d Cir. 2017)	13
---	----

RULE

Fed. R. Evid. 702	13
-------------------------	----

OTHER AUTHORITIES

CMS, “INSTRUCTIONS FOR COMPLETING THE PRESCRIPTION DRUG PLAN BID PRICING TOOL FOR CONTRACT YEAR 2018” (Apr. 7, 2017), https://www.cms.gov/medicare/health-plans/ medicareadvtspeccratestats/bid-pricing-tools-and-instructions- items/bpt2018	12
CMS, Medicare Part D – Direct and Indirect Remuneration (Jan. 19, 2017), https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct- and-indirect-remuneration-dir	12, 24
Medicare Part D Spending Data, https://data.cms.gov/summary-statistics-on- use-and-payments/medicare-medicaid-spending-by-drug/medicare- part-d-spending-by-drug	8
Part D Payment System, https://www.medpac.gov/wp-content/uploads/ 2021/11/medpac_payment_basics_21_partd_final_sec.pdf	11, 22
Report of the Advisory Committee on Evidence Rules (May 15, 2022)	18

PRELIMINARY STATEMENT

Dr. Rena Conti continues to press the economically and scientifically dubious claim that the lifesaving Valsartan-containing drugs (“VCDs”) at issue in this litigation were “worthless” because they contained trace impurities and should not have been sold—a theory that is belied by the expert judgment of the FDA, the opinions of patients, third-party payors (“TPPs”), health insurers themselves, and common sense. Relying on this overly simplistic assumption, Dr. Conti purports to calculate damages incurred by the TPP class members by multiplying the sales price of the VCDs and the quantity purchased, even though the data source on which she relies expressly disclaims its reliability to establish facts in a legal proceeding and its accuracy as to the purchase prices of medications. As explained below, all of Dr. Conti’s damages opinions are unreliable for several reasons and should be excluded.

First, Dr. Conti’s opinions do not fit the facts of the upcoming class trial, failing a threshold requirement of Rule 702. Dr. Conti purports to calculate damages based on the “point of sale” where each prescription was filled, but the subclass definitions point to the state where each TPP “paid any amount of money” for the VCDs. Because TPPs pay for VCDs through an intermediary such as a pharmacy benefits manager (“PBM”), and not at the point of sale, Dr. Conti’s model does not calculate damages fitting the subclass definitions and instead necessarily includes recoveries for TPPs that paid for VCDs outside of the subclass states and whose

claims are governed by other states' laws. Thus, Dr Conti's methodology is not capable of assisting the jury in determining damages.

Second, the lynchpin of Dr. Conti's opinions—i.e., that the VCDs were worthless—has no economic or scientific basis, as illustrated by Dr. Conti's deposition testimony. Although the Court previously admitted this theory, it reasoned that “[a]t [the] *class certification stage*, the methodology of [Dr. Conti] need not be perfect.” *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, No. 19-2875 (RBK/SAK), 2023 WL 1818922, at *51 (D.N.J. Feb. 8, 2023) (emphasis added). As the Advisory Committee on Civil Rules explained, however, the recent amendments to Rule 702 were promulgated in part to make clear that reliable application of a methodology is a question of admissibility, not merely weight. Dr. Conti's recent testimony that efficacious medications necessarily have some value, coupled with the revisions to Rule 702, highlight why the Court should exclude the “worthlessness” theory from trial.

Third, Dr. Conti's damages calculations—which are based either wholly or in part on IQVIA Xponent data that Dr. Conti concedes are merely a “best estimate of both quantities and of transactions”—are separately unreliable. (Dep. of Rena Conti (“Conti 2/1/24 Dep.”) 140:15-141:1, Feb. 1, 2024 (emphasis added) (Ex. 1 to Cert. of Jessica Davidson (“Davidson Cert.”).) Even a cursory comparison of that data and far more pertinent pharmacy transaction records (including MSP's own claims data)

demonstrates that the IQVIA-based calculations are wildly inflated, potentially by a measure of more than **\$1 billion**. And IQVIA itself has repeatedly cautioned that its data should not be used in the precise way Dr. Conti seeks to use it. Moreover, Dr. Conti ignores that the TPP class members were already reimbursed by the federal government for much of the money they spent on VCDs under the Medicare Part D program, further highlighting the inflated nature of her calculations.

BACKGROUND

Dr. Conti currently works as an associate professor at Boston University and is an affiliate of a “consulting and litigation support firm.” (Expert Decl. of Rena Conti, Ph.D. (“Conti Class Cert. Decl.”) ¶ 12, Nov. 10, 2021 (Davidson Cert. Ex. 2).) Dr. Conti has submitted several reports in this case, but only three are relevant to the upcoming class trial: her November 10, 2021 declaration, calculating damages for the TPP class as a whole across all theories of liability (*see* Conti Class Cert. Decl.); her February 3, 2023 declaration, calculating the purported damages incurred by the TPP class based solely on IQVIA Xponent data and the named plaintiff’s damages based on its assignors’ claims data (*see* Damages Expert Decl. of Rena Conti, Ph.D. (“Conti Class Rep. Decl.”), Feb. 3, 2023 (Davidson Cert. Ex. 3)); and her December 1, 2023 report recalculating purported class damages based on a mix of IQVIA data and pharmacy claims data (*see* Suppl. Damages Expert Decl. of Rena Conti, Ph.D. (“Conti New Decl.”), Dec. 1, 2023 (Davidson Cert. Ex. 4)). Dr. Conti

later “supplement[ed]” her December 1, 2023 report on December 18, 2023—more than two weeks after the deadline for plaintiffs’ supplemental damages report—with a spreadsheet that purported to “allocate” her recalculated damages by state, without any accompanying explanation.

I. Dr. Conti’s Worthlessness Assumption

All of Dr. Conti’s calculations rest on the same fundamental premise: that the VCDs the TPPs paid for are worthless because they were adulterated and did not have a “legitimate supply curve.” (*See* Conti Class Cert. Decl. ¶¶ 39-46; Conti Class Rep. Decl. ¶¶ 3-4; Conti New Decl. ¶¶ 1, 4.) Dr. Conti has never cited any economic literature supporting her views about legitimate supply curves or adulterated drugs having no value; nor could she identify any such literature in her deposition. (Dep. of Rena Conti (“Conti Class Cert. Dep.”) 124:16-127:3, Feb. 10, 2022 (Davidson Cert. Ex. 5).)

In her July 2023 deposition, Dr. Conti testified that economic value, to her, is equal to the “price paid.” (Dep. of Rena Conti (“Conti Class Rep. Dep.”) 19:16-20:5, July 13, 2023 (Davidson Cert. Ex. 6).) Dr. Conti further insisted that “market goods” with “market prices” are valued based on price paid, pointing to two otherwise identical apartments in New York City and Philadelphia as a “great example” of how identical goods can have different economic values. (Conti Class Rep. Dep. 20:20-22:1.) According to Dr. Conti, two otherwise identical products purchased at

“Costco” and “the most expensive drugstore” in “Manhattan” would have different economic values (*id.* 20:9-18), and two identical prescription pills purchased in “Manhattan” and “Louisiana” similarly would have different economic values (*id.* 24:7-22). Dr. Conti also reiterated her view that “economic value” does not take into account what happens after purchase, since economic value is determined “based on the price that is paid for the product.” (*Id.* 31:5-11.) As Dr. Conti explains, the fact that two people have very different experiences and levels of satisfaction with a product does not alter its economic value since they “both paid exactly the same price for it.” (*Id.* 29:7-30:3.) Accordingly, by Dr. Conti’s reasoning, economic value is a static value based solely on the price paid.

II. Dr. Conti’s Damages Calculations

While Dr. Conti uses two different data sets to calculate two vastly different class-wide damages amounts, and a third dataset to calculate the named plaintiff’s damages, her methodology for all three calculations is the same. In short, Dr. Conti “total[s] the quantity of at-issue [VCDs] purchased . . . and multipl[ies] it by the [point-of-sale] cost incurred.” (Conti Class Cert. Decl. ¶¶ 57, 61; *see also* Conti Class Rep. Decl. ¶ 8; Conti New Decl. ¶ 4.)

A. The Class Calculations

Dr. Conti has conducted two different damages calculations for the TPP class trial. Initially, she used IQVIA Xponent data alone for both the quantity and price

numbers. (*See* Conti Class Cert. Decl. ¶ 71; Conti Class Rep. Decl. ¶¶ 11, 13.) Using the IQVIA-only method, Dr. Conti calculated that the TPP class suffered \$1,336,744,346 in damages nationwide. (*See* Conti Class Rep. Decl. at 6.) She did not provide separate calculations for each subclass; nor did she purport to allocate the total by state (she did provide separate aggregate totals for each defendant).

Dr. Conti more recently provided a revised damages calculation, which uses a mixed dataset, still relying on IQVIA data for the quantity sold but now using pharmacy claims data consisting of more than 580 million real-world VCD transactions from nine pharmacy defendants (Albertsons, CVS, Express Scripts, Humana, Kroger, Optum, Rite Aid, Walgreens, and Walmart) to calculate average prices. (*See* Conti New Decl. ¶¶ 6, 13.) The revised calculation is more than \$1 billion lower than her prior, IQVIA-only calculation: \$319,015,400. (*See* Conti New Decl. at 11.) The reason for the disparity is that the IQVIA data merely contains “summaries of pharmaceutical claims,” purportedly including the “full cost” paid for the at-issue VCDs, according to Dr. Conti (Conti Class Cert. Decl. ¶ 71), while pharmacy claims data consists of “transaction-level sales of the at-issue Valsartan products, including the amount that consumers and third-party payors paid and the quantity that was dispensed” (Conti New Decl. ¶ 6). In short, the two datasets have wildly different average prices for the same medications because only one of the two

datasets—the pharmacy claims dataset—provides actual transactions reflecting the negotiated price charged for each VCD at the point of sale.

Although Dr. Conti claims that IQVIA Xponent data accurately represents the price a TPP pays at the pharmacy, IQVIA itself disagrees. As explained by IQVIA’s own guidance regarding the “T Price” field of its data, “a notable portion of pharmacies report list price in this field rather than the amount collected” at the pharmacy. (Ex. 9 to 9/20/23 Dep. of Wayne Gibson, at 1 (Davidson Cert. Ex. 7).) “[T]herefore,” IQVIA cautions, “the field should be used with that caveat in mind.” (*Id.*) Dr. Conti did not do so. (*See* Conti Class Rep. Dep. 183:3-16 (Dr. Conti claiming that “pharmacy transactions for generic drugs in the IQVIA data are largely reflected . . . in the T Price variable” of IQVIA data).) IQVIA has further cautioned that its data are “susceptible to error or variance,” and are therefore “not intended to be used as direct evidence or to establish any fact” in a legal proceeding or government investigation. (Conti 2/1/24 Dep. 92:19-93:7; *see also* Ex. 5 to Conti 2/1/24 Dep. at 3 (Davidson Cert. Ex. 8).) IQVIA also “offers no assurances that the IQVIA Data will be suitable for use as evidence” in any legal proceeding. (Ex. 5 to Conti 2/1/24 Dep. at 4.)

The IQVIA Information Services Published Specifications further state:

Although there is an inclination to view numerical data as fact, ***IQVIA information represents an estimate of measured activity and should be treated accordingly.*** To use it effectively, it is important to have a sufficient understanding of how the

information is sourced, processed, standardized, produced and reported. Further, *proper practice involves the use of IQVIA information in combination with other information* (e.g., knowledge based on skills and experience, other information and observations in the marketplace) *to make decisions*.

(Dep. of Wayne Gibson (“Gibson 2/5/24 Dep.”) 115:16-117:3 (emphases added) (Davidson Cert. Ex. 9); Ex. 23 to Gibson 2/5/24 Dep., at 1 (Davidson Cert. Ex. 10).)

The IQVIA data also report vastly higher drug prices than those found in multiple benchmarks, such as numbers reported by the Centers for Medicare and Medicaid Services (“CMS”) and in the claims data from the named representatives. (See Rebuttal Expert Decl. of Wayne T. Gibson (“First Gibson Decl.”) ¶¶ 69-79, June 28, 2023 (Davidson Cert. Ex. 11).)¹ Dr. Conti’s recalculation using the transaction-level pharmaceutical claims data—resulting in a \$1 billion difference in purported damages—also confirms that IQVIA reports significantly higher average prices than real-world transaction data. (See Conti New Decl. ¶ 11.)

For example, the pharmacy claims data reports that ZHP’s Valsartan 160mg—the single pill representing the highest quantity in the IQVIA data by far—has an average price of \$0.59 per pill, while IQVIA reports an average price of \$2.19 per pill: **3.71 times higher**. (See Conti New Decl. at 5, 8.) Despite the vast difference in reported prices, Dr. Conti stands by her original, \$1.3 billion damages calculation,

¹ See also Medicare Part D Spending Data, <https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug>.

claiming that her \$319 million “estimate is based on data that [she] think[s] has significant issues (Conti 2/1/24 Dep. 130:17-132:11 (Dr. Conti highlighting the “significant issues” she sees with the data underlying her \$319 million damages calculation)), and explaining that she only recalculated damages because plaintiffs’ attorneys asked her to do so (*see id.* 57:1-24). As discussed below, that stands in marked contrast to the approach Dr. Conti took when calculating the named plaintiff’s individual damages, where she selected real-world transaction data over IQVIA Xponent data.

Notably, IQVIA data only supplies Dr. Conti with the state of the pharmacy at which a drug is dispensed, not the state where the TPP paid for the medication. (*See* Conti 2/1/24 Dep. 67:3-69:2 (Dr. Conti confirming that when using the IQVIA quantity data, Dr. Conti was “looking at data from IQVIA as to . . . in what state the pharmacy was located,” and that “it’s the pharmacy state that the IQVIA data contains”).) As Dr. Conti acknowledged, TPPs did not “pay for” VCDs at the point of sale; rather, “there is a payment that is *made by the consumer*” at the point of sale, and “a calculation of whatever the health plan has to pay,” which is “charged” as a “reimbursement” to the TPP. (Conti 2/1/24 Dep. 35:22-37:14 (emphasis added).) Dr. Conti provides no data identifying when or where the TPPs “paid any amount of money” to “reimburse” these “charges.” Typically, an intermediary like a PBM “pays for the drug directly and then seeks repayment” from a client like a

TPP. (See ECF [2571](#), ¶ 110.) See also *In re Niaspan Antitrust Litig.*, 67 F.4th 118, 123 (3d Cir. 2023). Accordingly, in many instances, TPPs pay for medications where the PBM is located, not where the pharmacy is located. And even in cases where the TPPs may pay the pharmacy directly, Dr. Conti supplies no data source indicating that TPPs make payment to the brick-and-mortar location where an individual prescription was filled rather than the pharmacy's headquarters, which may be in another state. In short, Dr. Conti's "charges" at the point of sale say nothing about where the TPPs paid for the VCDs at issue.

B. The Named Plaintiff's Calculation

For the named plaintiff, Dr. Conti follows largely the same equation but instead uses "claims data produced by MSP." (Conti Class Rep. Decl. ¶ 7.) Although Dr. Conti had IQVIA Xponent data for the named plaintiff's assignors (Emblem and Summacare), she rejected the IQVIA Xponent data in favor of the real-world claims data to calculate the named plaintiff's damages. As Dr. Conti explains, "[u]nlike IQVIA Xponent data, which does not capture each individual consumer or TPP purchase, and is instead an aggregated summary of pharmaceutical claims by product, state, month, and payor, the MSP claims data shows transaction-level sales of the at-issue valsartan products, including the amount that the third-party payors paid and the quantity dispensed." (*Id.*) Dr. Conti never compared those calculations to the result from using IQVIA data (*see* Conti Class Rep. Dep. 189:12-15), and

claims that any differences between these two datasets would only be “slight” (*id.* 192:4-18). In fact, IQVIA data results in a damages figure three or even four times higher than using MSP’s claims data. (*See* First Gibson Decl. at 26-28.)

III. Dr. Conti’s Point-of-Sale Method

In calculating the cost of a pill, Dr. Conti only takes into account what happens at “the point of sale.” (Conti Class Rep. Decl. ¶ 6.) According to Dr. Conti, buying a pharmaceutical is like being in a car accident—if someone is “hit in a car accident on the highway” and their “car is totaled, [they] suffered injury,” regardless of whether someone is actually out any money. (Conti Class Rep. Dep. 150:23-151:4.) As a result, Dr. Conti does not take into account the several ways that TPPs were reimbursed by CMS for their purchases of VCDs, such as Medicare Part D.

Under Medicare Part D, CMS requires TPPs to provide a bid at the start of each coverage year generally detailing what products they will provide their beneficiaries, how much they expect to pay and how much they propose to charge CMS to provide those benefits.² Based on that bid, CMS determines how much to provide the TPP as a direct subsidy and what premium enrollees must pay to receive

² Part D Payment System, at 2-3, https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_partd_final_sec.pdf.

the proposed benefits.³ CMS also makes several additional payments to TPPs, such as:

- ***Low-Income Cost-Sharing Subsidies (“LICS”).*** CMS subsidizes Part D cost-sharing obligations for beneficiaries with low incomes and assets.
- ***Individual Catastrophic Reinsurance.*** For beneficiaries who have reached the catastrophic coverage limit—a preset amount of spending above which the beneficiary has very little responsibility—CMS pays 80% of the costs, the TPP pays 15% and the beneficiary pays 5%.
- ***Risk-Sharing Reconciliation.*** CMS compares the direct subsidy it provided to the TPP throughout the year to the actual costs the TPP incurred on behalf of beneficiaries, either providing additional payments or recouping some profits.

In making these subsidy determinations, CMS relies on each TPP’s Prescription Drug Event (“PDE”) data.⁴ The PDE data lists payments that are subject to the catastrophic coverage phase and low-income subsidies and thus partially covered by CMS. Dr. Conti did not consider PDE data in checking her damages calculations. (*See* Conti 2/1/24 Dep. 110:12-20 (Q: “Have you used the PDE data to

³ *Id.* at 1-3.

⁴ *See* CMS, “INSTRUCTIONS FOR COMPLETING THE PRESCRIPTION DRUG PLAN BID PRICING TOOL FOR CONTRACT YEAR 2018,” at 7 (Apr. 7, 2017), <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/bid-pricing-tools-and-instructions-items/bpt2018> (the information submitted by TPPs in the bid “[m]ust reconcile in an auditable manner to the plan-level Prescription Drug Event (PDE) data”); *see also* CMS, Medicare Part D – Direct and Indirect Remuneration (Jan. 19, 2017), <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir> (“Part D drug cost information—including the gross drug cost, LICS, and plan liability amount for each year—is available from the Part D PDE data.”).

try and validate the IQVIA Xponent data . . . as it relates to the price?” A: “Why would I do that?”).)

ARGUMENT

Under recently amended Fed. R. Evid. 702, plaintiffs have the burden of “demonstrat[ing] to the Court that it is more likely than not” that their expert’s opinions are “based on sufficient facts or data”; are the “product of reliable principles and methods”; and reflect a “reliable application of the principles and methods to the facts of the case.” Fed. R. Evid. 702. “[O]ne purpose of the amendment was to emphasize that ‘[j]udicial gatekeeping is essential’” *In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, MDL No. 3043, 2023 U.S. Dist. LEXIS 224899, at *49-50 & n.27, --- F. Supp. 3d ---- (S.D.N.Y. Dec. 18, 2023) (citation omitted); *see also In re Zolofit (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 792 (3d Cir. 2017) (“courts serve as gatekeepers for expert witness testimony” and must scrutinize “[b]oth an expert’s methodology and the application of that methodology” before admitting it under Rule 702). The Court should exercise its gatekeeping function and exclude Dr. Conti’s opinions for multiple reasons.

I. DR. CONTI’S CLASS-WIDE CALCULATIONS DO NOT FIT THE FACTS OF THE UPCOMING CLASS TRIAL.

“It is well-established that an expert opinion must be tailored to the specific facts of the case to have any value.” *United States v. Zimmerman*, 277 F.3d 426, 433 n.4 (3d Cir. 2002); *see also Ctr. City Periodontists, P.C. v. Dentsply Int’l, Inc.*, 321

F.R.D. 193, 202 (E.D. Pa. 2017) (“fit” requires that an expert’s testimony “be relevant for the purposes of the case and must assist the trier of fact”). Relatedly, a “model purporting to serve as evidence of damages in [a] class action must measure only those damages attributable to” the legal theory at issue in the class action. *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013); *see also Ctr. City Periodontists*, 321 F.R.D. at 204 (“[A] model purporting to serve as evidence of damages in this class action must measure only those damages attributable to that theory.”) (citation omitted).

Dr. Conti’s opinions fail these requirements because her damages calculations do not fit the three trial subclasses. Her first trial damages calculation is an aggregate nationwide damages calculation totaling \$1,336,744,346 in putative damages, broken out by manufacturer and drug type but not by state. (*See* Conti Class Rep. Decl. at 6.) Her second trial damages calculation is likewise an aggregate nationwide damages calculation totaling \$319,015,400, again broken out by manufacturer and drug type but not by state. (*See* Conti New Decl. at 11.) Dr. Conti then belatedly produced on December 18, 2023—17 days after the deadline for her supplemental damages report—a spreadsheet purporting to allocate the TPP damages (and consumer damages) by state for the second calculation, but not the first.⁵ Not only

⁵ Dr. Conti’s Class Certification Declaration included tables purporting to provide state allocations and subclass calculations, but the groupings do not match
(*cont’d*)

was Dr. Conti's state allocation untimely, but it was also unaccompanied by any opinions, conclusions or explanations setting forth any actual calculation of damages for any of the three subclasses. Thus, Dr. Conti has never supplied a damages calculation that fits the three trial subclasses.

Nor can such a calculation be extracted from Dr. Conti's untimely "allocation" spreadsheet because the subclasses certified for trial are defined by the state where each TPP "paid any amount of money for" the VCDs, while Dr. Conti admits her data sources cannot tie VCD transactions to the states where TPPs paid for the VCDs. This is so because the IQVIA data on which Dr. Conti relies reflects "the *pharmacy* state," not the location where TPPs make the relevant payments. (Conti 2/1/24 Dep. 67:3-13 (emphasis added); *see also id.* 68:14-69:2 (Dr. Conti confirming that she was "looking at data from IQVIA as to where the pharmacy was located").)⁶ And, as Dr. Conti further admits, the point of sale data reflects, at most, only the payment "made by the consumer" and the "reimbursement" that was "charged" to

the certified subclass definitions and the totals do not match her first damages calculation. (*See* Conti Class Cert. Decl. at Att. C.2, E.2, F.2.)

⁶ Dr. Conti submitted an errata sheet in another case claiming that the "STATE" field in the IQVIA Xponent data set "reflects the *prescriber's* location the vast majority of times." *See* Mem. of Law in Supp. of Defs.' Mot. to Exclude Test. of Dr. Rena Conti at 3, *In re Novartis & Par Antitrust Litig.*, No. 1:18-cv-04361-AKH, ECF 489 (S.D.N.Y. Jan. 11, 2022) (emphasis added) (citation omitted) (Davidson Cert. Ex. 12). The state of a prescriber also does not tell the jury where a TPP is located, much less where it actually paid for the medication that was dispensed.

the TPP, not where the TPP made its payment or where the pharmacy received its payment. (Conti 2/1/24 Dep. 35:22-37:14.) While consumers pay for medications at the pharmacy, TPPs more typically pay for medications via a PBM, which may or may not be located in the TPP's home state or the state where the pharmacy is located. As a result, there is a fundamental mismatch between Dr. Conti's model, the certified subclasses and the applicable law. *See Ctr. City Periodontists*, 321 F.R.D. at 204 (excluding "model [that] does not distinguish between damages attributable to the specific breach alleged in this case or 'something else'"). This alone requires exclusion of her opinions.

II. DR. CONTI'S OPINION THAT THE VCDS WERE WORTHLESS IS UNRELIABLE.

"The core of Dr. Conti's" opinions in this litigation is that a drug containing any impurities—even if the purported contamination does not undermine the safety of the medication—"can have no supply curve, and is therefore worthless." *In re Valsartan*, 2023 WL 1818922, at *15. This Court previously acknowledged defendants' argument that such a theory rested on "sophomoric economics and lack[ed] consideration of drug purchasers' health rationales for continuing to ingest minimally contaminated drugs." *Id.* The Court also considered but declined to follow persuasive authority holding that a "worthlessness" theory of loss "is not a defensible position" where—as here—the plaintiffs' expert "acknowledge[s] that [the medication] was enormously beneficial to many patients." *In re Rezulin Prods. Liab.*

Litig., 210 F.R.D. 61, 68-69 (S.D.N.Y. 2002) (“Plaintiffs’ contention that everyone who took [the prescription drug] Rezulin sustained an ascertainable loss presumes that Rezulin was worthless. But that is not a defensible position.”).⁷

The Court nonetheless admitted Dr. Conti’s opinion for class certification purposes, holding that “[a]t [the] class certification stage, the methodology of an expert need not be perfect or even legally correct.” *In re Valsartan*, 2023 WL 1818922, at *51. The Court reasoned that “[t]o the extent that there is disagreement over the models . . . that question is best answered by a jury”—i.e., essentially, that defendants’ challenge implicated the weight (rather than admissibility) of Dr. Conti’s fundamental opinion. *Id.* at *15 n.13, *51. The Court also found that Dr. Conti’s opinion had “achieved validation” in *Blue Cross Blue Shield Ass’n v.*

⁷ The Court stated that *In re Rezulin* is “not on point” because it “concern[ed] standing and class certification.” *In re Valsartan*, 2023 WL 1818922, at *15, *51. However, the Court misperceived the point of that decision, which is that the kind of theory being pressed in this litigation is simply not viable. Indeed, ample other authority (including in the TPP context) has essentially recognized as much at all stages of litigation. *See, e.g., Am. Fed’n of State Cnty. & Mun. Emps., Dist. Council 47 Health & Welfare Fund v. Ortho-McNeil-Janssen Pharms., Inc.*, 857 F. Supp. 2d 510, 515-16 (E.D. Pa. 2012) (granting manufacturers summary judgment on consumer-protection and unjust enrichment claims where the TPPs “paid for an effective pain killer, and [their members] received just that—the benefit of [their] bargain.”) (citation omitted); *Sergeants Benevolent Ass’n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 20 F. Supp. 3d 305, 334 (E.D.N.Y. 2014) (defendants were entitled to summary judgment on consumer-protection claims asserted by TPPs; theory of injury “assumes that [p]laintiffs would not have had to pay for any antibiotics at all had no misrepresentations been made. There is simply no evidence to support this highly dubious proposition.”).

GlaxoSmithKline LLC, No. 13-4663, 2019 WL 4751883, at *8-9 (E.D. Pa. Sept. 30, 2019), which similarly admitted Dr. Conti’s “worthlessness” theory in another TPP case and rejected the defendants’ argument that Dr. Conti’s analysis was “superficial and conclusory” as more appropriate for cross-examination, *id.* at *8.

The *BCBS* reasoning was erroneous at the time and is all the more so now, given the revisions to Rule 702, which were intended to clarify that methodological flaws are matters of weight, not admissibility. As one federal appeals court has explained, it is an “abdication of [the] gatekeeping role” to sidestep close review of an expert’s opinions based on tenuous assertions that these are “questions of weight and not admissibility.” *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 284 (4th Cir. 2021) (quoting advisory committee’s note to draft amendment to Rule 702); *see also* Report of the Advisory Committee on Evidence Rules, at 6 (May 15, 2022) (“The Committee concluded that in a fair number of cases, the courts . . . essentially treat[] these questions as ones of weight rather than admissibility, which is contrary to the Supreme Court’s holdings that under Rule 104(a), admissibility requirements are to be determined by [the] court under the preponderance standard.”).

Defendants’ challenges to Dr. Conti’s opinions implicate their admissibility (not weight) because her opinions defy basic economics and are essentially foreclosed by her own deposition testimony. Most fundamentally, as Dr. Conti explained in her deposition, any product that “has a market price . . . must have

some . . . economic value.” (Conti Class Rep. Dep. 26:2-9; *see also id.* 20:9-22:1; *id.* 29:15-30:9.) Dr. Conti simultaneously claims that because the at-issue VCDs were adulterated and people were unaware of that fact, the “economic value that [TPPs] paid is not what was delivered.” (*Id.* 107:2-22.) But her opinion completely ignores that there *could* have been a market price buyers would have paid for an efficacious drug with minimal contamination and no additional side effects. In fact, Dr. Conti was forced to concede in her deposition that the “clinical benefit of a product affect[s] its economic value” and “by definition” is “reflected in the demand curve” of the product. (Conti Class Rep. Dep. 110:11-18.) Accordingly, Dr. Conti’s own testimony belies her claim that the VCDs were worthless since there is likely *some* price buyers would have paid for an efficacious drug with de minimis contamination.

Dr. Conti’s recent testimony also underscores the illogical nature of her related opinions that damages are based solely on purchase price and assessed only at the time of sale. According to Dr. Conti, because the price paid “var[ies] depending on where the product was purchased,” identical medications purchased “at Costco” and “in Manhattan at the most expensive drugstore” would have resulted in different losses. (Conti Class Rep. Dep. 20:6-18.) And because Dr. Conti asserts that “economic value is assigned at the time of the product purchase,” nothing that occurs after the time of purchase affects the value that someone gets from a product.

(*Id.* 78:18-79:5; *see also id.* 30:11-31:11.) For example, Dr. Conti claimed that because “[p]eople purchase products in anticipation of the expected benefit cost,” it does not matter what someone’s *actual* experience is with a product; if it provides them no joy or satisfaction, it still has the same value to that consumer as it would to a consumer who loves the product and considers it a prized possession. (*Id.* 29:15-30:3.)

The upshot of Dr. Conti’s testimony is that a purportedly contaminated VCD sold outside of the United States and not governed by the Food, Drug, and Cosmetic Act (“FDCA”) would have had economic value, while the same exact medication sold in the United States is completely worthless. Moreover, under Dr. Conti’s approach, if a VCD were purchased in a country where it could be legally sold but was subsequently brought into the United States, the medication would still have “economic value” because that metric is “assigned at the time of the product purchase,” while an identical pill purchased in the United States and sitting in the exact same medicine cabinet would have zero value. (Conti Class Rep. Dep. 78:18-79:5.) Dr. Conti’s ruminations are not just highly subjective and lacking in economic or scientific support, but they are also facially absurd, “which any average person could readily recognize as preposterous.” *Johnson Elec. N. Am. Inc. v. Mabuchi Motor Am. Corp.*, 103 F. Supp. 2d 268, 286 (S.D.N.Y. 2000).

In sum, Dr. Conti's recent deposition testimony highlights the illogical and unreliable nature of her fundamental theory that the VCDs were worthless, further requiring exclusion of her opinions.

III. DR. CONTI'S DAMAGES CALCULATIONS ARE UNRELIABLE.

Even if Dr. Conti's worthlessness opinion were valid and her methodology fit the class definition, Dr. Conti's calculations would still be unreliable for multiple reasons. First, Dr. Conti failed to account for the fact that many TPPs did not sustain any out-of-pocket losses since they were already reimbursed by the federal government for purchasing the at-issue VCDs. And second, the IQVIA Xponent dataset on which Dr. Conti relied is highly inaccurate, as evidenced by IQVIA's own guidance, Dr. Conti's revised damages calculation, and Dr. Conti's admission that her use of the IQVIA data amounts to mere guesswork. Indeed, Dr. Conti's selection of real-world claims data over IQVIA Xponent data when calculating the named plaintiff's damages amount exposes the incoherence of her preference for IQVIA Xponent data over claims data when calculating class-wide damages.

A. Dr. Conti's Estimated Damages Are Wildly Overbroad Because She Did Not Consider Various Offsets Under Medicare Part D.

As the Third Circuit has explained, "[i]gnoring 'the real world'" can "render[] [an expert] opinion inadmissible." *Elcock v. Kmart Corp.*, 233 F.3d 734, 756 (3d Cir. 2000); *see also Edison Wetlands Ass'n v. Akzo Nobel Chems., Inc.*, No. 08-419 (FSH), 2009 WL 5206280, at *6 (D.N.J. Dec. 22, 2009) (an "expert's

assumptions . . . cannot ignore the ‘real world’”). Dr. Conti’s analysis does just that because it starts and stops at “the point of sale.” (Conti Class Rep. Decl. ¶ 6.) According to Dr. Conti, buying a purportedly adulterated pharmaceutical is like being in a car accident—if someone is “hit in a car accident on the highway” and her “car is totaled, [she] suffered injury,” regardless of whether she was reimbursed for that injury. (Conti Class Rep. Dep. 150:23-151:4.) In Dr. Conti’s opinion, if someone “purchase[d] a product” and got “a full rebate for it but . . . paid the money at the point of sale,” he or she would still be injured. (*Id.* 150:15-151:6.) Dr. Conti’s myopic approach to valuation and loss is neither realistic nor reliable.

First, Dr. Conti ignores that under Medicare Part D’s “bid” system (a hallmark of the program’s reimbursement process), CMS provides “direct subsid[ies]” to TPPs throughout the year that directly affect the amounts they actually pay for medications.⁸ Despite professing to be “a special government adviser” for CMS for “many years” (Conti Class Rep. Dep. 119:13-18), Dr. Conti was not even aware of that system and, accordingly, did not take it into account in coming to her calculations (*see id.* 120:7-9). That is a fundamental defect because, as even Dr. Conti was forced to concede, “[i]f a third party payor ends up spending more than” what they estimate they will spend, “CMS help[s] to bridge the difference.” (*Id.*

⁸ Part D Payment System, at 2-3, https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_partd_final_sec.pdf.

126:21-127:4.) The fact that Dr. Conti did not consider whether (and, if so, to what extent) CMS might have done so with respect to the TPPs in this case illustrates the overbroad nature of her calculations, which are not tethered to reality.

Second, Dr. Conti also disregarded the effects of specific subsidies paid to cover individual drug purchases. While the data Dr. Conti used may show a specific purchase price or a specific amount charged to a TPP (or its PBM) for a drug at the point of sale, CMS makes payments to cover portions of those costs, and the relevant subsidy is often not identified at the point of sale. For example, Dr. Conti did not consider the effect that Low-Income Cost-Sharing Subsidies, or LICS, would have had on a TPP's final VCD cost, even though she conceded at her deposition that "the plan pays" the cost of a drug on purchase and then is "*reimbursed* . . . by the federal government." (Conti Class Rep. Dep. 130:11-131:3.) "[I]n other words, the plan pays for the dispensed prescription by the pharmacy and then the plan is reimbursed by . . . CMS at some later point in time." (*Id.*) Thus, TPPs never actually had any obligation to pay—and, in fact, did not spend any money on—portions of VCDs on behalf of beneficiaries whose costs were covered by the LICS. Yet, under Dr. Conti's methodology, the TPPs would still be entitled to the full price paid at the time of purchase.

Third, Dr. Conti's methodology also fails to consider the cost implications of the catastrophic coverage phase of Medicare Part D. Under Medicare Part D, a TPP

will cover 49% of the cost of a drug when a beneficiary is in the coverage gap phase, but only 15% once they have spent enough to reach the catastrophic coverage phase.⁹ Because it is not always apparent at the time of purchase whether a beneficiary has reached the catastrophic coverage phase, a TPP may initially and erroneously cover 49% of costs at the point of sale rather than the 15% they are actually responsible for. Although such a mistake is ultimately identified and reconciled when CMS reimburses the TPP, Dr. Conti ignores such reimbursements, just as she ignores amounts correctly covered by CMS but not reflected in the record of the point of sale transaction (or in IQVIA's data). (*See* First Gibson Decl. at 32-35.)¹⁰

The import of these opinions is a grossly over-inflated model: if a covered plan spends \$100 on a VCD, and CMS covers \$80 of the purchase because the TPP was only supposed to spend \$20 on the medicine, Dr. Conti would award that plan \$100, even though the TPP is only out \$20. This approach is not only economically unsound, but would effectively turn tort law—the purpose of which is to

⁹ (*See* First Gibson Decl. at 32 & n.45 (citing The Medicare Part D Prescription Drug Benefit: Fact Sheet, Kaiser Family Foundation, September 2016).)

¹⁰ As explained by CMS's own guidance, Part D sponsors will also often "receive[] additional compensation after the point-of-sale that serves to ***change the final cost of the drug*** for the payer" in the form of direct or indirect remuneration. CMS, Medicare Part D – Direct and Indirect Remuneration (Jan. 19, 2017), <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir> (emphasis added). Dr. Conti similarly did not take direct or indirect remuneration into account.

compensate, not enrich—on its head. *See Durosky v. United States*, No. 3:CV-07-1828, 2008 WL 5104850, at *6 (M.D. Pa. Dec. 1, 2008) (“The objective of compensation in tort law is ‘to place the plaintiff in the same economic position as would have been his if the injury had not occurred.’”) (citation omitted).

B. Dr. Conti’s Reliance On IQVIA Data For Calculating Class-Wide Damages Is Unreliable.

All of Dr. Conti’s class damages calculations are also inadmissible because the IQVIA dataset on which Dr. Conti relies is fundamentally incomplete, inadequate and ultimately unreliable. It is axiomatic that an expert who “fail[s] to apply [her] own methodology” does not satisfy Rule 702’s reliability requirement. *See Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 268-69 (2d Cir. 2002) (excluding proposed expert who failed to control for certain variables that he acknowledged needed to be considered); *see also Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 561 (W.D. Pa. 2003) (“Because consistency is a hallmark of the scientific method . . . experts must be required to satisfy their own standards of reliability.”) (collecting cases). Dr. Conti’s reliance on the IQVIA data flouts this principle because: (1) IQVIA itself expressly cautions against using its data to establish facts in any legal proceeding due to its potential unreliability, as illustrated by the inaccurate price data Dr. Conti uses to calculate damages under her IQVIA-only method; and (2) the data cannot exclude non-Medicare Part D government plans that Dr. Conti claims must be excluded under her own methodology.

First, the IQVIA data are not a reliable metric for “total amount paid” in legal proceedings—as illustrated by the more than **\$1 billion** difference in damages Dr. Conti calculated when using IQVIA’s survey-based data versus her transaction-level claims data calculations. As IQVIA explains, its data are “susceptible to error or variance,” are “not intended to be used as direct evidence or to establish any fact” in a legal proceeding, and come with “no assurance” that they “will be suitable for use as evidence.” (Conti 2/1/24 Dep. 92:19-93:7; *see also* Ex. 5 to Conti 2/1/24 Dep. at 3.) Similarly, IQVIA cautions those who purchase its Xponent data that “a notable portion of pharmacies report list price . . . rather than the amount collected” at the pharmacy in its price field, and the field should therefore “be used with that caveat in mind.” (Ex. 9 to Dep. of Wayne Gibson at 1.)

Notably, even Dr. Conti describes IQVIA as “provid[ing] . . . the **best guess estimate** of reimbursement for these drugs.” (Conti 2/1/24 Dep. 139:6-13 (emphasis added); *see also, e.g., id.* 143:5-14 (“IQVIA is the best **guess** of quantities and reimbursements”) (emphasis added).) An expert’s opinions cannot be based on a reliable foundation when even she admits it is not. *See, e.g., Second Amend. Arms v. City of Chicago*, No. 10-cv-4257, 2020 WL 1157347, at *11-12 (N.D. Ill. Mar. 10, 2020) (excluding expert who “essentially admitted that he was missing key data[,] . . . based his assumptions on a lack of facts, rather than on reliable ones” and “admitted other problems with his data”); *Okla. Land Holdings, LLC v. BMR II*,

LLC, No. CIV-17-1036-D, 2020 WL 1236307, at *5 (W.D. Okla. Mar. 13, 2020) (excluding expert who “admit[ted] during his deposition testimony that his assumptions are unreasonable”); *Sines v. Darling Ingredients Inc.*, No. 19-19121, 2023 WL 3841741, at *11 (D.N.J. June 6, 2023) (excluding damages expert who “conceded that data from local tax assessors, multiple listing services, and other internet services are not necessarily accurate, and . . . believe[d] that he has encountered inaccurate information from the Jersey City tax assessor”); *see also Okla. Land Holdings, LLC*, 2020 WL 1236307, at *5 (excluding expert who “admitted he developed his opinions expressly for the purpose of testifying” and “admit[ted] during his deposition testimony that his assumptions are unreasonable”).

Dr. Conti’s most recent damages declaration—in which she compares the average prices from the transaction-level pharmacy claims data to IQVIA’s listed average prices—illustrates that use of IQVIA’s data is in fact an exercise in guesswork rather than a methodologically sound approach to calculating damages (*see* Conti New Decl. at 4-5, 7-8):

- ***ZHP Defendants.*** IQVIA data reports that Valsartan 160mg has an average price per pill of \$2.19 per pill, ***3.71 times more*** than the \$0.59 per pill in the pharmacy claims data.
- ***Teva Defendants.*** IQVIA data reports that Valsartan-HCTZ 320-25mg has an average price per pill of \$1.22 per pill, ***4.2 times more*** than the \$0.29 per pill in the pharmacy claims data.
- ***Torrent Defendants.*** IQVIA data reports that Amlodipine Valsartan-HCTZ 10-320-25mg has an average price per pill of \$5.94 per pill, ***1.96***

times more than the \$3.03 per pill in the pharmacy claims data.

These examples are by no means exhaustive. Of the 31 different medications for which Dr. Conti lists average prices from IQVIA and the pharmacy claims data, the IQVIA data reported higher average prices for **29 of the 31**, generating a more than \$1 billion differential in proposed damages. The sheer magnitude of the disparity demonstrates the inflated nature of Dr. Conti's proposed damages and confirms why IQVIA itself cautions against using its data in court proceedings. *See Lippe v. Bairnco Corp.*, 99 F. App'x 274, 279 (2d Cir. 2004) (affirming exclusion of expert who "failed to explain why her 'comparable companies' and DCF analyses did not yield similar results").

While Dr. Conti claimed in her deposition that this disparity could result from the pharmacy data including a smaller sample size than the IQVIA data, that late excuse does not save her opinions. (*See* Conti 2/1/24 Dep. 111:1-18 ("[T]he analysis that I did to look at the pharmacy data was largely to understand that when I had more claims in the pharmacy data, it approximated the price of the IQVIA data.").) Dr. Conti testified that the pharmacy claims data do not include purchases from "mom-and-pop pharmacies" and "mail order" prescriptions. (Conti 2/1/24 Dep. 111:1-113:17.)¹¹ But the parties do know the actual sales data for Emblem and

¹¹ Dr. Conti has not presented the results of any such analysis or provided statistical calculations to back up that claim, and "nothing in either *Daubert* or the
(cont'd)

Summacare, and recalculating damages for those assignors with IQVIA data results in a measure of damages ***three or even four times higher*** than using the actual claims data. (See First Gibson Decl. ¶¶ 73-80; see also Conti 2/1/24 Dep. 136:12-19 (Dr. Conti confirming that the MSP claims data includes “the price that they paid for each of the[] at-issue transactions”).) This belies the claim that the huge disparity is simply from the “mom-and-pop pharmacies” and retail transactions purportedly missing from the pharmacy claims data—and confirms that the IQVIA dataset is not reliable for calculating class damages.

Moreover, Dr. Conti’s belated preference at deposition for the IQVIA dataset over real-world claims data is contradicted by her own earlier calculation, when she selected the Emblem and Summacare claims data over the IQVIA data for Emblem and Summacare to calculate the named plaintiff’s individual damages. Presented with the same choice for the named plaintiff that she now has for the entire class, Dr. Conti chose the “claims data produced by MSP” to calculate the named plaintiff’s damages, reasoning that IQVIA Xponent data “does not capture each individual consumer or TPP purchase, and is instead an aggregated summary of pharmaceutical claims,” whereas the claims data “shows transaction-level sales of

Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

the at-issue valsartan products, including the amount that the third-party payors paid and the quantity dispensed.” (Conti Class Rep. Decl. ¶ 7.) Despite having access to a pharmacy claims dataset of more than 580 million transactions that would enable her to bring the same “transaction level sales” approach to bear for her class-wide calculation, Dr. Conti has expressed a preference for the IQVIA-based calculation and its inflation of damages by more than \$1 billion. Dr. Conti’s own prior work reveals that this choice is nakedly litigation-motivated and cannot withstand Rule 702 scrutiny.

Second, Dr. Conti’s class calculations are separately unreliable because the IQVIA data do not exclude certain payments that Dr. Conti claims should be excluded under her own methodology. To satisfy the “Valsartan TPP Class Definitions and Exclusions,” Dr. Conti excluded claims paid by “the following state and federal government entities (based on plan categories or plan names in the Xponent data): CHIP, federal assistance programs, Medicare Parts A and B, state assistance programs (e.g., ADAP), Tricare, Department of Veterans Affairs, Indian Health Service, state employee plans (city and county plans are not excluded), and worker’s compensation.” (Conti Class Cert. Decl. ¶ 75.) However, Dr. Conti again ignored the express limitations of the IQVIA data with regard to such non-compensable payments.

For example, documentation provided by IQVIA describes two different notations of “Model Type” for payments that Dr. Conti included in her class calculations—“UNKNOWN” and “UNSPEC” (meaning “unspecified”).¹² As IQVIA explains, the “UNKNOWN” category represents those “scripts that are third party but [have] *no* available identifiers to link to a Payer, PBM or Plan,” and “UNSPEC” represents “[s]cripts for a Payer that are unable to be reported at the Plan level.”¹³ However, approximately 12% of the prescription drug costs in Dr. Conti’s class-wide damages calculation fall into one of those two categories, creating a substantial risk that Dr. Conti is including payments that she intended to exclude from her damages calculation. (*See* First Gibson Decl. at 28.) And Dr. Conti’s second calculation compounded the error because she failed to identify and exclude the same types of non-class members (i.e., state assistance programs and state employee plans) when she filtered the pharmacy claims dataset. (*See* Second Gibson Rep. ¶¶ 32-39.) Because there is no way to exclude such payments from Dr. Conti’s calculations, the IQVIA data do not constitute a sufficiently reliable basis for Dr. Conti’s proffered methodology. For this reason as well, the IQVIA data Dr. Conti used are over-inclusive, further establishing the unreliability of her calculations.

¹² IQVIA Plan Model Type Definitions and Method of Payment Classifications, at 8 (Davidson Cert. Ex. 13).

¹³ *Id.* (emphasis added).

CONCLUSION

For the foregoing reasons, the Court should exclude the opinions of plaintiffs' damages expert, Rena Conti, from the upcoming TPP Trial.

Dated: February 12, 2024

Respectfully submitted,

By: /s/ Jessica Davidson

SKADDEN, ARPS, SLATE, MEAGHER &
FLOM LLP

Jessica Davidson (NY Bar No. 6034748)

*Liaison Counsel for Manufacturer
Defendants*

Allison M. Brown (NJ Bar No. 044992012)

One Manhattan West

New York, New York 10001

Phone: (212) 735-3222

Fax: (917) 777-3222

jessica.davidson@skadden.com

allison.brown@skadden.com

Nina R. Rose (DC Bar No. 975927)

1440 New York Avenue, N.W.

Washington, D.C. 20005

Phone: (202) 371-7000

Fax: (202) 661-0525

nina.rose@skadden.com

Attorneys for Zhejiang Huahai

Pharmaceutical Co., Ltd., Huahai U.S.,

Inc., Princeton Pharmaceutical Inc., and

Solco Healthcare U.S., LLC

/s/ Gregory E. Ostfeld

Gregory E. Ostfeld

GREENBERG TRAURIG, LLP

Tiffany M. Andras

77 West Wacker Drive, Suite 3100

Chicago, Illinois 60601
Tel: (312) 456-8400
ostfeldg@gtlaw.com
andrast@gtlaw.com

Lori G. Cohen, Esq.
Victoria Davis Lockard
Steven M. Harkins
Terminus 200
3333 Piedmont Rd., NE, Suite 2500
Atlanta, Georgia 30305
Tel: (678) 553-2385
Fax: (678) 553-2386
cohenl@gtlaw.com
lockardv@gtlaw.com
harkinss@gtlaw.com

*Attorneys for Teva Pharmaceuticals
USA, Inc., Teva Pharmaceutical
Industries Ltd., Actavis LLC, and
Actavis Pharma, Inc.*

/s/ Alexia R. Brancato
Alexia R. Brancato
Devora W. Allon
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, New York 10022
Tel: (212) 446-5967
Fax: (212) 446-6460
alexia.brancato@kirkland.com
devora.allon@kirkland.com

*Attorneys for Defendants Torrent
Pharmaceuticals Ltd. and Torrent
Pharma, Inc.*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 12, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson
Jessica Davidson